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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use In Animal Feeds; Narasin and Nicarbazin With Bacitracin Methylene Disalicylate**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health, a Division of Eli Lilly & Co. The NADA provides for combining approved narasin/nicarbazin (1:1 fixed ratio) and bacitracin methylene disalicylate (BMD) Type A medicated articles to make combination drug Type C medicated broiler chicken feeds for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, a Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140-926 that provides for combining approved narasin/nicarbazin (1:1 fixed ratio) Maxiban® and BMD Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. The feeds contain 27 to 45 grams per ton (g/t) each of narasin and nicarbazin and 4 to 50 g/t BMD. The feeds are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency. The

NADA is approved as of January 4, 1999, and the regulations are amended in 21 CFR 558.76, 558.363, and 558.366 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

This approval is for use of approved Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, nicarbazin, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required for making a Type B or C medicated feed as in this application. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by a requirement for manufacture in a licensed feed mill. Therefore, use of narasin/nicarbazin and BMD Type A medicated articles to make Type C medicated feeds as in NADA 140-926 requires manufacture in a licensed feed mill.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

#### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3)(xix) to read as follows:

**§ 558.76 Bacitracin methylene disalicylate.**

\* \* \* \*

(d) \* \* \*

(3) \* \* \*

(xix) Narasin and nicarbazin as in § 558.366.

3. Section 558.363 is amended by adding paragraph (d)(2)(ii) to read as follows:

**§ 558.363 Narasin.**

\* \* \* \*

(d) \* \* \*

(2) \* \* \*

(ii) Nicarbazin and bacitracin methylene disalicylate as in § 558.366.

4. Section 558.366 is amended in the table in paragraph (c) under entry “27 to 45” by alphabetically adding an entry for “Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50” to read as follows:

**§ 558.366 Nicarbazin.**

\* \* \* \*

(c) \* \* \*

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate by 046573.	000986

Dated: 1/22/99

January 22, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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 Center for Veterinary  
 Medicine

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